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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,255	12/18/2003	Michael John Rutter	CHM-019	1904
38155	7590	10/04/2004	EXAMINER	
HASSE GUTTAG & NESBITT LLC 7550 CENTRAL PARK BLVD., MASON, OH 45040			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/740,255

Applicant(s)

RUTTER, MICHAEL JOHN

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/18/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the endotracheal tube is closer to the skin between the patient's nose and upper lip proximally than distally must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 9, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Beran (4,516,293).

Beran in an adjustable collar (10) for a nasal or oral endotracheal tube, discloses:

- a smooth first surface (14) for contacting the skin of a patient using the endotracheal tube,
- a support section (26) attached to the first surface (14), and
- a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (Fig. 4).

With respect to claim 4, Beran discloses the collar for use with a nasal endotracheal tube (Col. 1, lines 17-23), wherein said collar is tapered in the region where it contacts the endotracheal tube.

With respect to claim 5, Beran discloses the collar is shaped so that the endotracheal tube is closer to the skin between the patient's nose and upper lip proximally than distally; it would be inherent that the collar of Beran meets the claimed

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functional limitations as the collar supports the tube prior to insertion into nasal or oral cavity.

With respect to claim 9, Beran discloses an adjustable collar (10) comprising:

- a smooth first surface (14) for contacting the skin of the patient,
- a support section (26) attached to the first surface (14), and
- a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (12, Fig. 4), and
- lateral extensions (18-21) from the collar for securing the collar to the head of the patient.

With respect to claim 12, Beran discloses wherein the lateral extensions have a bi-lobed appearance (18-21).

With respect to claim 13, Beran discloses wherein the lateral extensions (18-21) have a smooth surface that contacts the patient's skin (at 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 6-8, 10, 11, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beran (4,516,293).

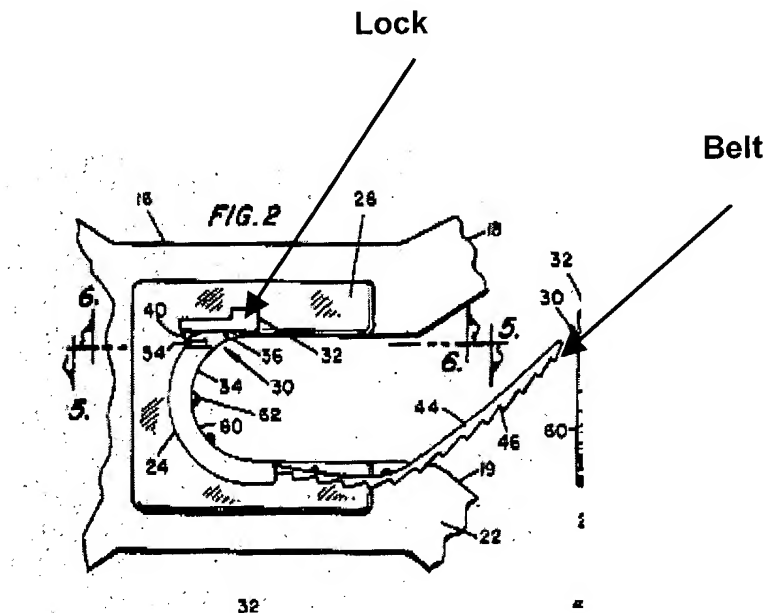
The difference between Beran and claim 2 is the collar being made of a semi-rigid, non-irritating plastic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the collar made of a semi-rigid, non-irritating plastic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration (*In re Leshin*, 227 F.2d 197, 125 USPQ 416) and because in the medical field it is known to use semi-rigid, non-irritating materials for cannula holding devices because the material is durable and non-irritating material is used because many patient's using the device often have the tubes in for extended periods of time and therefore a non-irritating material helps maintain skin integrity and lessen skin breakdown.

With respect to claims 3, 6, and 10 note rejection of claim 2 above.

With respect to claims 7 and 11, Beran discloses a retainer strip underlies the domes (44), as for the strip being a plastic note rejection of claim 2 above.

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With respect to claim 8, Beran discloses wherein the strip comprises a lock at one end (32) and a belt at the other end (see illustration of Fig. 2 below).



With respect to claim 14, see rejection of claims 1 and 9 above. With respect to the limitation of at least one strap attached to the lateral extensions Beran discloses holders include an adhesive surface or other attachment means including straps and hook and fabric arrangements (Col. 1, lines 49-52). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the adhesive for strap attachment means as disclosed by Beran.

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With respect to claim 15, Beran discloses that hook and fabric arrangements are known therefore it would have been obvious to one of ordinary skill in the art to have at least one strap of hook and loop refastenable material as such material is well known in the art (Col. 1, lines 49-52).

With respect to claim 16, it would be inherent that the at least one lateral strap connects the at least one strap attached to the lateral extensions (18-21).

With respect to claim 17, note rejection of claim 2 above.

With respect to claim 18, Beran discloses wherein the lateral extensions (18-21) have a bi-lobed appearance.

With respect to claim 19, Beran discloses a retainer strip (44) underlies the domes (62), as for the limitation of being plastic note rejection of claim 2 above.

With respect to claim 20, Beran does not disclose two straps. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have two straps, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art and the use of two straps would provide additional securing means to a user.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cite to show collar devices for nasal or oral tubes: 6,561,192; 6,634,359; 6,010,484; 6,029,668; 5,782,236; 5,806,516; 5,653,232; 5,551,421; 5,341,802; 5,295,480; 5,069,206; 4,874,380; 4,832,019; 4,744,358; 4,449,527; 4,249,529.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Examiner
Art Unit 3743
September 29, 2004